AUG - 4 2004

K 033399

510(k) SUMMARY

Submitter's name: Electrical Geodesics, Inc.
1600 Millrace Drive, Suite 307
Eugene, OR 97403
541-687-7962

Date summary prepared: June 21, 2004

Device name:

Proprietary name:	Geodesic EEG System™ Series 100
Common or usual name:	EEG machine
Classification name:	Electroencephalograph, 84 GWQ Class II, 21 CFR 882.1400.

Legally marketed device for substantial equivalence comparison:

The predicate device for this submission is the Geodesic EEG System™ Model 200 submitted by Electrical Geodesics, Inc. and cleared for marketing under 510(k) #K012079.

Description of the device:

The Geodesic EEG System™ Series 100 products, also known as the GES Series 100, are digital electroencephalography systems (EEG) that can accommodate up to 256 electrodes. The GES Series 100 is computer controlled and capable of acquiring, storing, and displaying data. It includes electrodes, amplifiers, a central processing unit, and software. The GES Series 100 uses some components from the previously submitted and cleared Geodesic EEG System™ Model 200. It blends these with components from another manufacturer. The combined product is new and has not been previously submitted to FDA.

The GES Series 100 products are composed of the following components. The Geodesic Sensor Net® is a dense array of scalp electrodes designed to allow rapid application in an even distribution across the head and is the preferred electrode system. Standard EEG electrodes and cap-type electrodes purchased from other vendors may also be used. The Neurotravel WIDE consists of multiple amplifiers for physiological signals that are fully software controlled. The central processing unit can be either Mac based or PC based. Mac based systems use the proprietary Net Station® software package to control acquisition of data, storage of digital data, and manipulation of data for review. PC based systems use the Neurotravel Win software package to control similar system features. Neither software package performs any diagnosis. Additional components of the system are an articulated arm with extended cable, isolation transformer, rack system, various cables, standard components of personal computer (monitor, keyboard, and mouse), photic stimulator, video EEG, electrolyte solution, and disinfectant.

Intended use of device:

The Geodesic EEG System Series 100 products are intended to measure and record the electrical activity of the patient's brain. They can be used on adults, children, and infants.

Technological characteristics:

The technological characteristics of the Geodesic EEG System Series 100 are similar to those of the predicate device. Each product is a digital EEG system that is software controlled, and that can acquire, display, and record EEG data. The preferred electrodes for both systems are the Geodesic Sensor Nets. The amplifiers are different and so some differences in electrical parameters exist. The GES Series 100 can be based on either a Mac or a PC, with matching software, while the predicate device is based on a Mac. None of the software involved with these products analyzes the data independent of the operator or provides diagnosis.

Testing conducted:

Testing was conducted to ensure compliance with international standards related to electroencephalographs. The general safety standard used was: IEC 601.1 including Amendments 1 and 2. The electromagnetic compatibility standard was EN60601-1-2(1993). The electroencephalograph standards were EN 60601-2-26 (1994) and EN 60601-2-40 (1998). The biocompatibility standard was ISO 10993.

Performance testing:

Comparative performance testing and clinical evaluations were not submitted as part of this 510(k).

Previously Submitted Materials Being Withdrawn

The following materials which were submitted in the Original 510(k) or in the Supplement are being withdrawn or revised because of the withdrawal of the EP indication for use. All other parts of the previous submissions still support this application.

Original 510(k)

Section	Status
Section 4	Withdraw statements on page 16 describing Win software support of EP/ERP.
Appendix IX	Neurotravel Win Technical Manual has been revised to delete references to EP. Revised and complete manual can be found in Appendix IV of the current submission.

Supplement

Section	Status
Cover Letter	Withdraw answer to question 1.
Appendix I	Withdrawn

All other previously submitted material supports the EEG indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 4 2004

Electrical Geodesics, Inc.
c/o Ms. Linda J. Bovard, B.S. RAC
R.S. McQuate & Associates
29611 Simmons Road
Eugene, Oregon 97405

Re: K033399
Trade/Device Name: Geodesic EEG System™ Series 100 (GES Series 100)
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: GWQ
Dated: June 22, 2004
Received: June 25, 2004

Dear Ms. Bovard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033399

Device Name: Geodesic EEG System™ Series 100 (GES Series 100)

Indications For Use:

The Geodesic EEG System™ Series 100 products are intended to measure and record the electrical activity of the patient's brain. They can be used on adults, children, and infants.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K033399